

REVISED, FEBRUARY 8, 1999

IN THE UNITED STATES COURT OF APPEALS

FOR THE FIFTH CIRCUIT

No. 97-40591

In Re: NORPLANT CONTRACEPTIVE PRODUCTS LIABILITY LITIGATION

THERESA HARRISON, ET AL.,

Plaintiffs,

THERESA HARRISON; ANDREA ELAINE HAUGHT,

Plaintiffs-Appellants,

versus

AMERICAN HOME PRODUCTS CORPORATION, doing

business as Wyeth-Ayerst Laboratories, a

Delaware Corporation; WYETH LABORATORIES

INCORPORATED,

Defendants-Appellees.

BARBARA WOODS, ET AL.,

Plaintiffs,

KRISTY YOUNGBLOOD,

Plaintiff-Appellant,

versus

AMERICAN HOME PRODUCTS CORPORATION, doing

business as Wyeth-Ayerst Laboratories, a

Delaware Corporation; WYETH LABORATORIES

INCORPORATED,

Defendants-Appellees.

CRYSTAL McDONALD, ET AL.,

Plaintiffs,

BEVERLY McDANIEL,

Plaintiff-Appellant

versus

AMERICAN HOME PRODUCTS CORPORATION, doing

business as Wyeth-Ayerst Laboratories, a

Delaware Corporation; WYETH LABORATORIES,

INCORPORATED,

Defendants-Appellees.

WENDY BOEHM, ET AL.,

Plaintiffs,

JENNIFER L. BURTON,

Plaintiff-Appellant,

versus

AMERICAN HOME PRODUCTS CORPORATION, doing

business as Wyeth-Ayerst Laboratories, a

Delaware Corporation; WYETH LABORATORIES

INCORPORATED,

Defendants-Appellees.

Appeal from the United States District Court for the

Eastern District of Texas, Beaumont

January 29, 1999

Before JOLLY, DAVIS, and DUHÉ, Circuit Judges.

E. GRADY JOLLY, Circuit Judge:

The appellants in this matter (collectively referred to as "Harrison") are five plaintiffs who each suffered side effects from their use of the prescription contraceptive Norplant, manufactured by Wyeth Laboratories Incorporated, a company owned by American Home Products ("AHP"). They appeal a district court ruling for summary judgment in favor of AHP. The primary question presented on appeal is whether the learned intermediary doctrine should apply to the plaintiffs' claims. Because we find no error in the district court's ruling, we affirm. AHP cross-appeals the district court's denial of its motion for partial summary judgment based on the statute of limitations bar. Because we find that AHP is entitled to summary judgment, we need not address this issue on appeal.

I

This case involves litigation over the side effects of the contraceptive Norplant. Norplant is a long-term birth control method whereby the recipient has six thin capsules of the hormone progestin inserted just below the skin of her upper arm. Harrison claims that Norplant can also have significant, unwanted side effects.(1)

In this case, all five plaintiffs received Norplant from their personal physicians and each suffered side effects. On July 22, 1994, a class action was filed against AHP, as the parent entity of Wyeth Laboratories-- the manufacturer of Norplant, on behalf of "all adult women who have had Norplant inserted in their bodies and who have sustained damages." On December 8, 1994, the Judicial Panel on Multidistrict Litigation transferred all federal Norplant actions to the Eastern District of Texas for consolidated pretrial proceedings before Judge Richard Schell. Each of the plaintiffs in this matter subsequently filed individual actions in the Eastern District of Texas. On August 5, 1996, the court denied the plaintiffs' motion for class certification, deciding that class certification was premature and that bellwether trials were appropriate to determine whether the class should be certified under rule 23(c)(4). The plaintiffs in this case were selected for the first of three bellwether trials.

At the close of discovery, AHP moved for summary judgment and the district court granted the motion. The district court held that the learned intermediary doctrine applied to all of the claims filed by Harrison. Under that doctrine "when a drug manufacturer properly warns a prescribing physician of the dangerous propensities of its product, the manufacturer is excused from warning each patient who receives the drug. The doctor stands as a learned intermediary between the manufacturer and the ultimate consumer." *Alm v. Aluminum Co. of America*, 717 S.W.2d 588, 592 (Tex. 1986) (citations omitted). The district court concluded that, under the doctrine, AHP had no obligation to warn the end user of the potential side effects of Norplant. The district court then concluded that Harrison had failed to produce evidence that AHP had not properly notified the prescribing physicians of Norplant's potential side effects. Harrison now timely appeals.

II

Summary judgment is proper if "the pleadings, depositions, answers to interrogatories and admissions on file, together with affidavits, if any, show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c). A summary judgment ruling is reviewed de novo, applying the same criteria employed by the district court. *Conkling v. Turner*, 18 F.3d 1285, 1295 (5th Cir. 1994).

Harrison raises a number of objections to the district court's application of the learned

intermediary doctrine. First, Harrison argues that the learned intermediary doctrine cannot be applied to claims under the Texas Deceptive Trade Practices Act ("DTPA") as the doctrine is a common law defense and cannot be applied to a statute like the DTPA. Second, Harrison urges that even if the doctrine could be applied to the claims in this case, it should not as AHP marketed Norplant directly to the end users and that the end users relied on warnings (and the absence of warnings) provided by AHP's marketing rather than warnings provided by their physicians. Finally, Harrison argues that the doctrine should not apply because Norplant was required by the Food and Drug Administration ("FDA") to provide warnings about the side effects.

A

Harrison argues that the learned intermediary doctrine is inapplicable to the claims made under the DTPA.⁽²⁾ The district court did not address this issue below, apparently concluding that, because the DTPA claim was equivalent to the other common law claims, the learned intermediary doctrine should apply to it.

On appeal, Harrison argues that the learned intermediary doctrine is a common law defense, and that common law defenses may not be applied to the DTPA. Harrison's support for this argument comes from a line of cases spawned by the Texas Supreme Court's decision in *Smith v. Baldwin*, where that court stated: "The DTPA does not represent a codification of the common law. A primary purpose of the enactment of the DTPA was to provide consumers a cause of action for deceptive practices without the burden of proof and numerous defenses encountered in a common law fraud or breach of warranty suit." 611 S.W.2d 611, 616 (Tex. 1980).

Subsequent Texas cases have applied *Baldwin* to generally disallow the use in DTPA claims of both common law defenses and common law doctrines that affect the burden of proof. *Alvarado v. Bolton*, 749 S.W.2d 47, 48 (Tex. 1988)(barring use of doctrine of merger); *Weitzel v. Barnes*, 691 S.W.2d 598, 600 (Tex. 1985)(barring use of parole evidence rule and common law burden of proof); *O'Hern v. Hogard*, 841 S.W.2d 135, 137 (Tex. App.--Hous. 1992) (barring common law doctrine of new and independent cause); *Shenandoah Associates v. J & K Properties, Inc.*, 741 S.W.2d 470, 496 (Tex. App.--Dallas 1987, writ denied) (barring defense based on waiver and ratification); *Home Savings Association v. Guerra*, 720 S.W.2d 636, 644 (Tex. App.--San Antonio 1986) (barring estoppel defense), *aff'd in part, rev'd in part*, 733 S.W.2d 134 (Tex. 1987); *Roy E. Thomas Const. Co. v. Arbs*, 692 S.W.2d 926, 932 (Tex. App.--Fort Worth 1985) (barring defense of impossibility), *writ rev'd n.r.e. per curiam*, 700 S.W.2d 919 (Tex. 1985); *Joseph v. PPG Indus., Inc.*, 674 S.W.2d 862, 865-66 (Tex. App.--Austin 1984, writ rev'd n.r.e.) (barring defense of failure of consideration).

The Texas courts have also made clear, however, that at least some common law common law doctrines are applicable to the DTPA. *Joseph E. Seagram & Sons, Inc. v. McGuire*, 814 S.W.2d 385, 387-88 (Tex. 1991) (holding that, under the DTPA, no legal duty exists to warn of the health

risks of alcohol consumption because such risks are "within the ordinary knowledge common to the community"); *Autohaus, Inc. v. Aguilar*, 794 S.W.2d 459, 462 (Tex. App.--Dallas 1990) (permitting use of common law doctrine of "puffing" in DTPA claim), writ denied per curiam, 800 S.W.2d 853 (Tex. 1991); *Jenkins v. Steakley Bros. Chevrolet Co.*, 712 S.W.2d 587, 590 (Tex. App.--Waco 1986, no writ) (permitting DTPA suit to be barred by accord and satisfaction). In both *Seagram* and *Autohaus*, Texas courts therefore permitted a common law doctrine that defined the degree to which a seller is responsible for a consumer's reliance on the safety or quality of a sold product.

Harrison asserts, however, that the learned intermediary doctrine is a common law defense that should not be applicable to the DTPA under *Baldwin*. The basis for this conclusion arises from the following language in *Rolen v. Burroughs Wellcome Co.*, 856 S.W.2d 607, 609 (Tex. App.--Waco 1993 writ denied): "The 'learned intermediary doctrine' is distantly related to the tort concept of 'superseding cause.' Although the doctrine has never been recognized by the Texas Supreme Court, it has been adopted by intermediate appellate courts." Based on this language, Harrison argues that the doctrine is a common law defense inapplicable to the DTPA. To the extent that the learned intermediary doctrine is comparable to the tort concept of superseding cause, a credible argument can be made that, under *O'Hern*, the doctrine should not be applicable to the DTPA.

AHP responds, however, by arguing that the doctrine is not a defense but instead is "a rule of law that defines a pharmaceutical manufacturer's duty to provide adequate warnings with its products." AHP further supports its contention by noting that in three cases, the Texas courts, though admittedly not the Texas Supreme Court, have applied the learned intermediary doctrine to the DTPA. *Rivers v. American Home Products Corp.*, No. 342-160538-95 (Order dated 4/9/98) (Appellee's Record Excerpt Tab 4); *Bean v. Baxter Healthcare Corp.*, 1998 WL 104944, at *8 (Tex. App.--Houston [14th Dist.] 1998, no writ h.); *Jordan v. Geigy Pharmaceuticals*, 848 S.W.2d 176 (Tex. App.--Fort Worth 1992, no writ.). The most telling of these cases is *Rivers*, which applies the doctrine to the DTPA in the context of the same Norplant litigation addressed in this case.

While Texas courts have applied the learned intermediary doctrine to the DTPA, none of them have explicitly addressed the argument made by Harrison here. That Texas appeal courts have applied the doctrine in DTPA cases despite the edict not to apply common law defenses to the DTPA, nevertheless suggests the result a Texas court would likely reach if presented with this issue.⁽³⁾ We therefore make an Erie guess that the Texas Supreme Court would hold that the learned intermediary doctrine is not a common law defense but instead a common law doctrine, like those in *Seagram* and *Autohaus*, that establishes the degree to which a prescription drug manufacturer is liable for an end user's reliance on the effects of a prescription drug. Because we hold that the learned intermediary doctrine is not a common law defense like those barred by *Baldwin*, Harrison's argument that the district court incorrectly applied it to the DTPA fails.

Harrison's other two arguments, each of which have been thoroughly addressed by the district court below, also lack merit. We briefly address each in turn.

Harrison argues that the learned intermediary doctrine should not apply in this instance given AHP's knowledge of Norplant's side effects and its conduct in marketing Norplant. Harrison argues that, for reasons of public policy, Norplant should have had a duty to warn the end user of Norplant's side effects because of the reduced role physicians play in selecting contraceptives for their patients. Harrison contends that the physician's reduced role invalidates the rationale of the learned intermediary doctrine because the patient cannot rely on the physician to provide an adequate warning. Although it may be true that physicians may seek to provide greater freedom to their patients in selecting an appropriate form of contraception, Norplant is nevertheless a prescription drug. The record makes it clear that physicians play a significant role in prescribing Norplant and in educating their patients about the benefits and disadvantages to using it. Harrison's argument therefore is unavailing.

Harrison also argues that because AHP engaged in "aggressive" marketing, AHP should be liable for not providing adequate warnings in conjunction with that marketing. This argument is critically weakened by the absence of any evidence on the record that any of the five plaintiffs actually saw, let alone relied, on any marketing materials issued to them by AHP.⁽⁴⁾ Given this deficiency, even if such an exception to the doctrine should apply, summary judgment would still be appropriate in this case. It seems clear, however, that even if the facts were in Harrison's favor, Harrison would still lose. Two of our cases applying Texas law in this area have concluded that, as long as a physician-patient relationship exists, the learned intermediary doctrine applies. *Hurley v. Lederle Laboratories*, 863 F.2d 1173, 1178 (5th Cir. 1988); *Swayze v. McNeil Laboratories*, 807 F. 2d 464 (5th Cir. 1987).

Harrison's next argument is that there should be an exception to the learned intermediary doctrine when the FDA has provided recommended warnings. To support this argument, Harrison relies on an Oklahoma Supreme Court case for the proposition that, when the FDA mandates that labeling information be provided to patients, the learned intermediary doctrine should not apply. *Edwards v. Basel Pharmaceuticals*, 933 P.2d 298 (Okla. 1997). The court reached this somewhat counter-intuitive result by concluding that, where the potential side effects of a prescription drug are so serious that the FDA places a requirement on the manufacturer to warn the end user, the rationale of the learned intermediary doctrine no longer applies.

At the outset, we find this conclusion to be puzzling. Our understanding of the rationale of the learned intermediary doctrine, at least in substantial part, is that it seeks to encourage the drug manufacturer to make available prescription drugs despite their potentially harmful side effects, by shielding the drug manufacturer from liability when the drug is prescribed by a properly trained physician. Why the learned intermediary doctrine should somehow be less applicable when the severity of the side effects encourages the FDA to promote additional labeling escapes us.

Regardless of the merits of the Oklahoma Court's holding, there are other reasons why it is not applicable to this case. First, although the state of Oklahoma has created this exception to the learned intermediary doctrine, there is no evidence that the Texas Supreme Court would be inclined to follow in that state's footsteps. In addition, the FDA has explicitly stated that its regulation should not affect civil tort liability for drug manufacturers and dispensers. FDA, Prescription Drug Products; Patient Labeling Requirements, 44 Fed. Reg. 40016, 40023 (July 6, 1979). Finally, even if we were permitted to create such an exception to the doctrine in Texas law, Harrison's argument in this case would still fail as the FDA did not mandate any sort of labeling for Norplant.

III

The only issue Harrison raises on appeal is whether the learned intermediary doctrine applies to her claims. For the foregoing reasons, it does. The judgment of the district court is therefore

A F F I R M E D.

1. 1These effects include severe headaches, mood swings, depression, nausea, acne, arm pain, numbness, breast tenderness, weight gain, hair loss, cramps, and bleeding irregularities, including amenorrhea.

2. 2Harrison alleges violations of Tex. Bus. & Com. Code §17.46(b)(5) ("representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have or that a person has a sponsorship, approval, status, affiliation, or connection which he does not"); (b)(7) ("representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another"); and (b)(23) ("the failure to disclose information concerning goods or services which was known at the time of the transaction if such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed"). Harrison also alleges violations of implied and express warranties under § 17.45(5) of the Act.

3. 3In *U.S. v. Johnson*, 160 F.3d 1061, 1063-64 (5th Cir. 1998), we recently addressed the degree to which we are bound by holdings of the Texas appeal courts. In this case, where no Texas Supreme Court case is directly on point, we may look to an appeal court holding for guidance if it is likely to be adopted by the Texas Supreme Court.

4. 4Harrison argues that although none of the plaintiffs were ever exposed to direct marketing, their physicians did show them videos and other materials prepared by AHP in explaining

Norplant to them. Those materials, however, were entirely within the control of the physician and AHP had no control over which, if any, of the materials were shown to the patient.